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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARIUS HAURI,
FRANK BLINKHORN, DAVID MACLEAN, LAWRENCE P. HUDON,
ROBERT SIMAS JR., and TROY M. DERBY

Appeal 2010-001363
Application 10/665,514
Technology Center 3700

Before JAMESON LEE, KARL D. EASTHOM, and JOSIAH C. COCKS,
Administrative Patent Judges.

COCKS, *Administrative Patent Judge*.

DECISION ON APPEAL

A. STATEMENT OF THE CASE

The real party in interest, Smiths Medical ASD, Inc. ("Smiths Medical"), appeals under 35 U.S.C. § 134(a) from a rejection of claims 1, 2, 4-6, 8-11, 13-21, 23-25, 27, and 28. We have jurisdiction under 35 U.S.C. § 6(b).

We *affirm-in-part*.

References Relied on by the Examiner

Landis	5,490,841	Feb. 13, 1996
Gyure et al. ("Gyure")	5,669,889	Sep. 23, 1997
Pressly, Sr. et al. ("Pressly")	7,014,622	Mar. 21, 2006
Hudon	7,156,825	Jan. 2, 2007
Johnson et al. ("Johnson")	2002/0010433	Jan. 24, 2002
Crawford et al. ("Crawford")	2002/0161336	Oct. 31, 2002

The Rejections on Appeal

The Examiner rejected claims 1, 2, 4, 9, 20, 21, 23, and 28 under 35 U.S.C. § 103(a)[1] as unpatentable over Crawford and Hudon.

The Examiner rejected claims 8 and 27 under 35 U.S.C. § 103(a) as unpatentable over Crawford, Hudon, and Landis.

The Examiner rejected claim 10 under 35 U.S.C. § 103(a) as unpatentable over Crawford, Hudon, and Gyure.

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[1] The Examiner's Answer states that the rejection is applied under "35 U.S.C. 102(e)." (Ans. 4:14.) However, review of the content of the rejection reveals that it is premised on a theory of obviousness based on the combined teachings of Crawford and Hudon. It is therefore evident that the citation of "102(e)" is in error and the rejection is based on 35 U.S.C. § 103(a). Smiths Medical also recognized that the rejection, though mistakenly labeled "102(e)," is applied under 103(a). (App. Br. p. 10, FN 2.)

The Examiner rejected claims 5 and 24 under 35 U.S.C. § 103(a) as unpatentable over Crawford, Hudon, and Johnson.

The Examiner rejected claims 11, 13-17, and 19 under 35 U.S.C. § 103(a) as unpatentable over Johnson, Crawford, Hudon, and Pressly.

The Examiner rejected claim 18 under 35 U.S.C. § 103(a) as unpatentable over Johnson, Crawford, Hudon, Pressly, and Landis.

The Invention

The invention relates to a safety needle assembly including a needle protecting sheath that is attached via a rotatable collar to a needle hub of the needle assembly. (Spec. 1:¶ 002.) Claim 1 is reproduced below (App. Br.[2] 24 Claims App'x.):

1. Safety apparatus, comprising:

a needle hub having a proximal portion and a distal portion, a needle extending from a distal end of said needle hub;

a collar rotatably mounted directly on the distal portion of said needle hub so as to be rotatable about said needle hub, said collar having a first engage mechanism at its inner circumferential surface;

a housing pivotally connected to said collar; and

a needle sheath having a proximal portion with a second engage mechanism at its outer circumferential surface, said first and second engage mechanisms fitted to each other when said sheath is fitted to said collar, said proximal portion having only one side in contact engagement to said collar for covering said needle extending from the distal end of said needle hub and said sheath is not in contact with said

[2] In this opinion, "App. Br." refers to the "Appellant's Substitute Brief on Ex Parte Appeal" filed September 2, 2009.

needle hub when said sheath is fitted to said collar and said first and second engage mechanisms are engaged to each other.

B. ISSUES

1. Did the Examiner correctly determine that, in connection with a safety needle assembly, Crawford and Hudon together teach a collar that is rotatably mounted directly to a needle hub?

2. Did the Examiner correctly determine that the prior art teaches first and second engage mechanism formed, respectively as a circumferential rib formed on the inner wall of a collar and a circumferential groove formed on the end of a sheath?

3. Did the Examiner correctly determine that the prior art discloses a needle hub with an end for connecting to a luer, *i.e.*, a luer end, and a "ring" surrounding the luer end which a user may readily grasp?

4. Did the Examiner correctly determine that in light of the prior art, it would have been obvious to incorporate a "window" into the surrounding "ring" of a needle hub which allows for viewing of the end of the needle hub?

5. Did the Examiner correctly determine that the prior art discloses a safety apparatus for a needle assembly including a pair of angled lips where the "respective angles of said lips being varied along the length of said housing to effect a guide for said needle to smoothly enter into said housing at an angle through said opening"?

6. Did the Examiner establish an adequate basis for rejecting claim 17 over the teachings of Johnson, Crawford, Hudon, and Pressly?

C. PRINCIPLES OF LAW

During examination, claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000.)

The broadest reasonable interpretation rule recognizes that before a patent is granted the claims are readily amended as a part of the examination process and that an applicant has the opportunity and responsibility to remove any ambiguity in claim meaning by making an amendment. *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004).

In a rejection based on multiple references, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

A person of ordinary skill in the art is presumed to have skills apart from what the prior art references explicitly say. *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418 (2007). One with ordinary skill in the art is also a person of ordinary creativity, not an automaton. *Id.* at 421.

The question of obviousness is not merely what the references expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made. *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976).

D. FINDINGS AND ANALYSIS

The Examiner rejected claims 1, 2, 4, 9, 20, 21, 23, and 28 over Crawford and Hudon and claims 5, 8, 10, 11, 13-19, 24, and 27 over those references together with one or more of Gyure, Landis, Johnson, and

Pressly. We address the claims in the following groupings: (1) claims 1, 2, 9, 10, 20, 21, and 28; (2) claims 4 and 23; (3) claims 8 and 27; (4) claims 5 and 24; (5) claims 6 and 25; (6) claims 11 and 16; (7) claims 13 and 14; (8) claim 15; (9) claim 17; and (10) claim 18.

Claims 1, 2, 9, 10, 20, 21, and 28

Claim 1 and 20 are independent claims. Claims 2, 9, and 10 are ultimately dependent on claim 1. Claims 21 and 28 are dependent on claim 20. The dependent claims are argued collectively with the independent claims. Claim 1 is directed to a safety apparatus. Claim 20 is drawn to a method of making a needle assembly. Each of claims 1 and 20 includes a feature concerning the rotatable mounting of a collar on a needle hub. In particular, in claim 1, the feature reads "a collar rotatably mounted directly on the distal portion of said needle hub so as to be rotatable about said needle hub." (App. Br. 24 Claims App'x.) In claim 20, the feature reads "rotatably mounting said collar directly on the distal portion of said needle hub so that said collar is rotatable about said needle hub." (*Id.* at 27.)

The Examiner found that Crawford discloses a safety apparatus and needle making method including needle hub 60 with needle 40 and collar 90 mounted to the needle hub. (Ans. 5:1-5.) The Examiner determined that Crawford's disclosure accounts for all the limitations of claims 1 and 20 with the exception of the above-quoted features. Specifically, the Examiner explained that while Crawford discloses that its collar is directly mounted on a needle hub, the mounting is not disclosed as being rotatable. (*Id.* at 6:1-2.) To make up for the deficiency, the Examiner relied on Hudon. Hudon discloses a safety adapter for a needle hub assembly. (Hudon Title.) The safety adapter includes a sleeve assembly with sleeve 2 that engages needle

hub 28 from which needle 48 extends. (*Id.* at 2:29-47; 3:6-8.) Sleeve 2 is described as being "rotatable" about the needle hub. (*Id.* at 3:35-36.) Hudon further describes that a needle protection housing 36 is attached to sleeve 2 via a collar portion 30 of the sleeve. (*Id.* at 2:48-61.) Hudon explains that its invention provides for a conventional needle hub to be retrofit with its inventive safety assembly and that such retrofit desirably allows rotation of the needle protection housing portion of the safety assembly with respect to a needle. (*Id.* at 4:17-21.)

The Examiner equated each of Hudon's sleeve 2 and Crawford's collar 90 with the "collar" element called for in Smiths Medical's claims. Smiths Medical does not dispute that those components of Hudon's and Crawford's inventions each constitute a collar. Although Crawford does not disclose that its collar is rotatable on the needle hub, in light of the teachings of Hudon, the Examiner reasoned that it would have been obvious to make Crawford's collar rotatable in the manner of the rotatable mounting described in connection with Hudon's sleeve. (Ans. 6:4-9.) The Examiner thus concluded that Smiths Medical's claims 1 and 20 are unpatentable over the combined teachings of Crawford and Hudon.

Smiths Medical contends that Hudon's disclosure in conjunction with mounting its sleeve 2 to its needle hub 28 does not constitute a teaching of rotatably mounting a collar on a needle hub. According to Smiths Medical, Hudon discloses that its sleeve 2 is "held fixedly to needle hub 28" through the friction fitting of needle cap 20 to the needle hub. (App. Br. 14:6-10.) Smiths Medical also contends that even if needle cap 20 is removed, "sleeve 2 continues to be fixedly held to hub 28." (*Id.* at 14:10-13.) Thus, Smiths Medical is of the view that because the mounting of Hudon's sleeve 2 to

needle hub 28 is allegedly un-rotatable in any situation with respect to a needle hub, that mounting cannot suggest rotatably mounting a collar to a needle hub.

We do not agree with Smiths Medical's view as it is based on an inaccurate assessment of the teachings of Hudon. Hudson establishes that its sleeve assembly is "held fixedly" only when "needle hub 28 coupled with needle cap 20." (Hudon 3:30-31.) That is evident because it is the operation of a portion of the needle cap (base portion 60) that interacts with each of needle hub 28 and sleeve 2 so as to frictionally join the hub, sleeve, and cap together. (*Id.* at 3:21-30.) There is, however, no disclosure that sleeve 2 must remain fixed with respect to needle hub 28 when the needle cap 20 is removed. (*See id.* at 3:60.) Indeed, contrary to Smiths Medical's assertion, Hudon makes explicit that the sleeve may at times rotate with respect to the needle hub, stating in particular that its disclosed assembly "has a sleeve 2 that is rotatable about the needle hub 28." (*Id.* at 3:35-36.) That sleeve in turn has an additional "collar 30" component which itself is also rotatable about sleeve 2. (*Id.* at 3:36-41.) Thus, a plain reading of Hudon's disclosure sets forth that its safety assembly incorporates at least two separate possible rotatable mounting configurations, *i.e.*, rotation of sleeve 2 with respect to needle hub 28 and rotation of collar 30 with respect to sleeve 2.

In rejecting Smiths Medicals claims, the Examiner relied on the disclosure of the first of those mounting configurations as a teaching that rotatably mounting a collar component with respect to a needle hub is a known and viable collar mounting configuration for a needle safety apparatus. That position is reasonable and in accord with Hudon's

disclosure. Smiths Medical's analysis of Hudon's teachings is inadequate to show that the Examiner's position is incorrect.

Smiths Medical also states that making Crawford's collar 90 rotatable with respect to its needle hub 60 would render Crawford's device "unusable." (App. Br. 14:28-31.) According to Smiths Medical, unless Crawford's collar 90 remains fixedly attached to needle hub 60 then needle sheath 50, which covers needle 40 and is threaded onto the collar 90, will be unable to be secured to the collar because the collar "would not stay still" if free to rotate. (*Id.* at 14:26-28.) Smiths Medical, however, does not offer any objective evidence for its statement, such as expert testimony. The statement is simply attorney argument. Such argument cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). Moreover, the record reflects that the level of skill in the art is such that one with ordinary skill would have known of multiple types of attachment techniques for joining components of a needle safety apparatus. Smiths Medical offers no credible reason why a skilled artisan would have had inadequate technical competence to join components that are intended to be joined. We reject Smiths Medical's argument that the Examiner's proposed combination of Crawford and Hudon would somehow render Crawford's device "unusable."

The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d at 425. Here, Crawford discloses that its collar 90 is mated with a needle hub via a technique which includes "any…mechanical fit." (Crawford 5: ¶ 0064.) Hudon discloses one known practice of mating a sleeve, *i.e.*, a collar, directly to a needle hub in which the sleeve is allowed

to rotate with respect to the hub. On this record, we conclude that a person of ordinary skill in the art, who is also one of ordinary creativity, *KSR Int'l Co.*, 550 U.S. at 421, would have readily appreciated that mounting the components of a collar to a needle hub, such as those of Crawford, may be accomplished by rotatably mounting the collar directly to the needle hub as required by Smiths Medical's claims 1 and 20.

We have carefully considered Smiths Medical's arguments but are not persuaded that they demonstrate any error in the Examiner's rejection of claims 1 and 20 based on the teachings of Crawford and Hudon. Accordingly, we sustain the rejection of claims 1 and 20. The patentability of dependent claims 2, 9, 10, 21, and 28 is not argued apart from claims 1 and 20. We also sustain the rejection of claims 2, 9, 10, 21, and 28.

Claims 4 and 23

Claim 4 is dependent on claim 1 and claim 23 is dependent on claim 20. Claims 1 and 20 each introduced a needle sheath that is connected to the collar. Each of claims 4 and 23 provide detail as to the arrangement of the "engage" mechanisms that enable the connection. In particular, the claims establish that a "first engage mechanism" of the collar is a "rib circumferentially formed" (claim 4) or a "rib formed circumferentially" (claim 23) at the inner wall of the collar. The claims also establish a "second engage mechanism" on the needle sheath that is a "groove formed circumferentially" (claim 4) or a "circumferential groove" (claim 23).

In accounting for claims 4 and 23, the Examiner pointed to Crawford's inner threads 97 as forming the required rib on the collar and external threads 56 as forming the required circumferential groove on the sheath. (Ans. 5:15-17; 11:17-20.) Smiths Medical disputes that those

structures identified by the Examiner are sufficient to meet the requirements of claims 4 and 23. According to Smiths Medical, its claims require structures that are "snapped together" and do not include structures that are threaded together as in Crawford. (App. Br. 16:13-18.)

We do not agree with Smiths Medical. During examination, claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Hyatt*, 211 F.3d at 1372. The claims do not require any particular engagement technique between the groove and rib, *i.e.*, that those features must be "snapped together." Although Smiths Medical's specification describes one embodiment in which a rib is "snap fitted" into a groove (Spec. 11:¶ 0038), it does not preclude other types of engagement. That is, it is not inconsistent with the specification that a groove and a rib may be engaged via other practices. The broadest reasonable interpretation rule recognizes that before a patent is granted the claims are readily amended as a part of the examination process and that an applicant has the opportunity and responsibility to remove any ambiguity in claim meaning by making an amendment. *In re Bigio*, 381 F.3d at 1324. If Smiths Medical intended that its claims include only "snap fitted" engagements, it could have amended the claims accordingly. It did not. We reject Smiths Medical's argument that its claims only encompass a "snapped together" engagement of a groove and a rib.

Turning to the Examiner's prior art rejection, we note that Smiths Medical's specification does not give the terms "rib" or "groove" any special meaning. We thus look to the ordinary meanings of those terms. The ordinary meaning of "rib" is "an elongated ridge." *Merriam Webster's Collegiate Dictionary* 1006 (10th ed. 1996). The ordinary meaning of

"groove" is "a long narrow channel or depression." *Id.* at 514. The claims therefore require an elongated ridge which is formed along the circumference, *i.e.*, the periphery, of the inner wall of the collar and a depression or channel which extends around the circumference of the sheath.

In rejecting Smiths Medical's claims, the Examiner explained that, given its broadest reasonable interpretation, the "rib" requirement is met by the "raised portion" of the thread which extends along the inner wall of collar 90. The Examiner also explained that the "groove" requirement is met by the "area in between the threads" on sheath 50. The Examiner's position is reasonable and in accord with the ordinary meaning of the terms of "rib" and "groove." Smiths Medical does not meaningfully articulate why or how that position is incorrect.

We have considered Smiths Medical's argument that the prior art does not disclose the circumferential groove and rib of its claims, but conclude that the argument is predicated on an incorrect assessment of the requirements of the claims. For the foregoing reasons, we are not persuaded of any error in the Examiner's rejection of claims 4 and 23 over Crawford and Hudon. We sustain the rejection of claims 4 and 23.

Claims 5 and 24

Claim 5 is dependent on claim 1 and claim 24 is dependent on claim 20. Claims 5 and 24 include additional limitations with respect to the needle hub introduced in claims 1 and 24. In particular, each of claims 5 and 24 add features directed to a "luer end" formed at a proximal end of the needle hub and a "ring" formed on the needle hub and surrounding the luer end which serves as a feature that may be readily grasped by a user. (App. Br. 24, 27-28 Claims App'x.)

In rejecting claims 5 and 24, the Examiner determined that the above-quoted features were lacking from the teachings of Crawford and Hudon and relied on the teachings of Johnson to make up for the shortcoming. Johnson discloses an adapter for attaching a needle to a "LUER LOK" receptacle, such as a syringe. (Johnson Abstract.) The Examiner, pointing to Johnson's Figures 2A-2E, determined that Johnson discloses a hub with a ring which may be grasped by a user. (Ans. 7:16-17.) In view of the teachings of Johnson, taken with Crawford and Hudon, the Examiner reasoned that claims 5 and 24 would have been obvious.

Smiths Medical contends that the combination of Crawford, Hudon, and Johnson has "no bearing" on the subject matter of claims 5 and 24. (App. Br. 18:6-8.) Smiths Medical's reasoning for that contention is that the "hub" disclosed in Johnson is not a "needle hub." Specifically, Smith Medical argues (App. Br. 18:19-21) (emphasis in original):

> [T]he hub that is disclosed in Johnson is a *syringe* hub to which, at best, a needle assembly may be mated. It is not the *needle* hub to which a needle assembly is mated per required in the claims of the instant invention.

Smiths Medical's argument, however, is misplaced. In the context of Smiths Medical's specification, a "needle hub" is a component which receives a needle and operates as a mechanism for mating the needle with a receptacle, such as a syringe. (Spec. 6: ¶ 0027.)

Although Johnson describes "hub 18" in connection with a structure that is affixed to the end of a syringe 14 (*e.g.*, Johnson 1: ¶ 0008), that is not the hub in Johnson that is referenced by the Examiner. The figures of Johnson relied on by the Examiner, *i.e.*, Figures 2A-2E, illustrate the configuration of adapter 40.

Figure 2C (reproduced below left) shows the components of the adapter which includes a fitting portion 44 receiving a medical instrument 46, such as a needle. (*Id.* at 3: ¶ 0042.) Surrounding fitting 44 is a cylindrical housing 42 configured such that it "facilitates handling of the adapter 40." (*Id.* at 3: ¶ 0037.) In use, adapter 40 is positioned on the end of syringe 14 in such a manner that "hub 18" of the syringe connects with fitting 44 so as to make a fluid connection between the syringe and needle 46 attached to the fitting. (*Id.* at 3: ¶ 0040; *see also* Fig. 2D reproduced right.) Adapter 40, in receiving needle 46, itself reasonably constitutes a "needle hub" and includes an outer cylindrical housing portion 42. As set forth in Smiths Medical's specification, a "ring" is cylindrical structure which surrounds a portion of the needle hub. (Spec. 6: ¶ 0029; Fig. 6.) Johnson's cylindrical housing 42 is ring which forms a portion of the needle hub and facilitates handling of the needle hub.

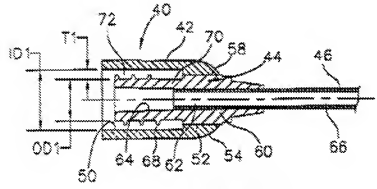


FIGURE 2C

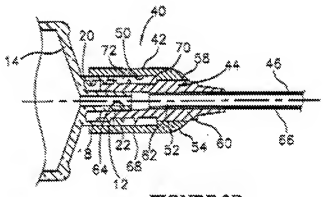


FIGURE 2D

The Examiner's assessment of the teachings of Johnson in determining the obviousness of claims 5 and 24 is reasonable and in accord

with its disclosure. Smiths Medical has not demonstrated that there is error in the Examiner's rejection of claims 5 and 24. Accordingly, we sustain the rejection of those claims over Crawford, Hudon, and Johnson.

Claims 6 and 25

Claim 6 is dependent on claim 5 and claim 25 is dependent on claim 24. Each of claims 6 and 25 adds the feature of a "window" formed in the ring of the needle hub which enables a user to view the luer end of the needle hub. In rejecting claims 6 and 25, the Examiner determined that Crawford, Hudon, and Johnson do not teach a window as required and turned to Pressly to account for that feature.

Pressly discloses a needle safety syringe for use with interchangeable needles. (Pressly Abstract.) Pressly's Figure 1 (below left) illustrates an embodiment of its invention. As shown in the figure, attached to barrel 6 of the syringe is a needle hub 2. The needle hub 2 receives the needle head 12 of needle 14 (see Fig. 2 right). Surrounding a portion of the needle hub is a structure termed "needle assembly 8." (Pressly 5:54-59.) Pressly describes that needle assembly 8 may be made transparent so as to allow viewing of the connection of needle head 12 and needle hub 2. (Pressly 7:35-43.)

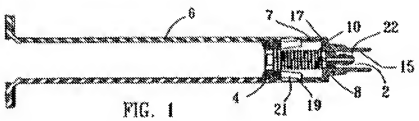


FIG. 1

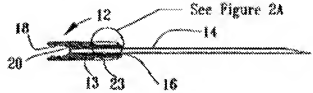


FIG. 2

The Examiner determined that the transparent needle assembly 8 of Pressly's safety syringe constitutes a window and reasoned that one with

ordinary skill in the art would have known to incorporate such a window into other safety devices involving syringes and needles. The Examiner concluded that in view of the teachings of Crawford, Hudon, Johnson, and Pressly, Smiths Medical's claims 6 and 25, including the feature of a ring with at least one window, would have been obvious. (Ans. 10:1-12.)

Smiths Medical challenges the Examiner's conclusion on the theory that Pressly's needle assembly, even if transparent, does not constitute the ring with a window that is required by its claims. Smiths Medical also contends that it "does not make any sense" to combine the teachings of Pressly, Crawford, Hudon, and Johnson. (App. Br. 20:5-15.)

We are not persuaded by Smiths Medical's contention. In a rejection based on the teachings of multiple references, the test for obviousness is not what any individual reference discloses, but is instead what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d at 425. Claims 6 and 25 were rejected based on the combined teachings of Crawford, Hudon, Johnson, and Pressly. Thus, the obviousness inquiry of claims 6 and 25 based on those references does not turn on whether any one of those references, *e.g.*, Pressly, individually discloses certain features of the claims, such as a ring surrounding a needle hub and provided with a window for viewing an end of the needle hub. Rather, the obviousness evaluation must take into account the *combined* teachings of the references.

Each of Crawford and Hudon teach that a needle and needle may be joined in some fashion when constructing a medical instrument, such as a syringe assembly. Johnson teaches that a cylindrical or ring shaped housing is desirably formed surrounding such a connection so as to facilitate

handling. Pressly makes clear the desirability of viewing the connection between the needle hub and a needle. To accomplish that purpose, in one embodiment of its invention, Pressly describes that a guide portion, *i.e.*, needle assembly 8, surrounding the connection may be made of a transparent material. Although a "window" generally connotes an opening, and a transparent material would not itself be viewed as an opening, a person of ordinary skill in the art is presumed to have skills apart from what the prior art references explicitly say. *See KSR Int'l Co.,* 550 U.S. at 418. One with ordinary skill in the art is also a person of ordinary creativity, not an automaton. *Id.* at 421. Furthermore, the question of obviousness is not merely what the references expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made. *In re Lamberti*, 545 F.2d at 750.

Pressly describes one embodiment in which the covering member of a needle hub and needle connection is transparent, however, that embodiment, and its transparent covering member, is described as an "alternative" to other embodiments. (Pressly 7:40-41.) When the covering structure is not transparent, *e.g.*, opaque, the desirability of viewing that which is covered still remains. The number of options available for allowing viewing of a component that is covered by another structure is limited. One with ordinary skill and creativity in the art would reasonably have appreciated that, if not transparent, the covering structure would need to include openings to allow for the desired viewing. In light of the teachings of the prior art, we conclude that it would have been obvious to incorporate at least one opening, *i.e.*, a window, in a ring surrounding a needle hub to allow for viewing of an end of the needle hub. Smiths Medical's argument that it

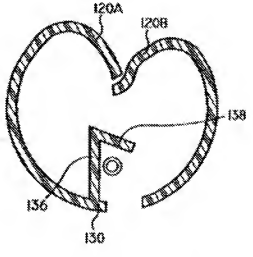
"does not make any sense" to combine the teachings of the prior art does not adequately account for how a person of ordinary skill and creativity in the art would have viewed the combined teachings of the references.

On this record, we conclude that in light of the teachings of the prior art, claims 6 and 25, including the requirement of at least one window formed in the a ring surrounding a needle hub, would have been obvious. We sustain the rejection of claims 6 and 25 over Crawford, Hudon, Johnson, and Pressly.

Claims 8 and 27

Claim 8 is dependent on claim 1 and claim 27 is dependent on claim 20. Each of claims 8 and 27 includes features directed to angled lips of housing that operate to guide a needle to enter the housing through an opening. In each claim, the lips are described as being angled toward the interior of the housing with the "respective angles of said lips being varied along the length of said housing to effect a guide for said needle to smoothly enter into said housing at an angle through said opening." (App. Br. 25, 28 Claims App'x.).

The Examiner rejected claims 8 and 27 over Crawford, Hudon, and Landis. Specifically, the Examiner relied on Landis' Figure 11 as showing the above-quoted feature of claims 8 and 27. (Ans. 12:6-10.) Landis' Figure 11 (right) shows a cross-sectional view of the housing of a sheath which receives a needle. Components 120A and 120B are described as doors which extend



along the housing and are angled in towards the interior of the housing for allowing a needle to enter the housing. (Landis 9:23-32.) The Examiner equated those doors to the lips required by the claims.

Smiths Medical generally contends that Landis does not show the angled lips required by claims 8 and 27, but does not meaningfully address the disclosure of Landis relied upon by the Examiner. Smiths Medical does not articulate why the angled doors or lips 120A and 120B, depicted in Figure 11 as being at different angles relative to each other along the housing and operating to guide a needle into the housing, do not reasonably meet the requirements of claims 8 and 27 pertaining to lips with respective angles that are varied and functioning to allow entry of a needle into the housing.

We are not persuaded of any error in the Examiner's rejection of claims 8 and 27 based on the teachings of Crawford, Hudon, and Landis. We sustain the rejection.

Claims 11 and 16

Claim 11 is an independent claim. Claim 16 is dependent on, and argued collectively, with claim 11. Claim 11 is directed to a "combination" of structural features and includes recitation of a needle hub with a surrounding ring having a window formed therein. Smiths Medical's argument with respect to claim 11 is largely the same as that presented in connection with claims 6 and 25. Like claims 6 and 25, claim 11 was rejected over the combined teachings of Johnson, Crawford, Hudon and Pressly.

We have considered Smiths Medical's arguments, but for essentially the same reasons discussed above in conjunction with claims 6 and 25, we

are not persuaded by those arguments. We sustain the rejection of claims 11 and 16 over Johnson, Crawford, Hudon, and Pressly.

Claims 13 and 14

Claims 13 and 14 are ultimately dependent on claim 11. Smiths Medical states that claims 13 and 14 add to claim 11 features similar in nature to those added to claims 1 and 20 by claims 4 and 23. Claim 13 adds that the needle sheath includes a "first engage mechanism" and the collar includes a "second engage mechanism" for connecting the sheath and collar. (App. Br. 26 Claims App'x.) Claim 14, dependent on claim 13, further adds that the needle sheath includes a "circumferential groove" and the collar includes a "circumferential rib." (*Id.*) Smiths Medical urges that the "same argument" set forth for claims 4 and 23 applies to claims 13 and 14. (*Id.* at 22:4-5.)

As with claims 4 and 23, claims 13 and 14 were rejected in-part over the teachings of Crawford, which, as discussed above, discloses a needle sheath with a first engage mechanism formed as a "rib" around the end of the sheath and a collar with the second engagement mechanism formed as a "groove" around an inner wall of the collar. We have considered Smiths Medical's argument but, for similar reasons given above with respect to claims 4 and 23, we are not persuaded that Smiths Medical has shown error in the Examiner's rejection of claims 13 and 14.

We sustain the rejection of claims 13 and 14 over Johnson, Crawford, Hudon, and Pressly.

Claim 17

Claim 17 is dependent on claim 11 and adds the following (App. Br. 26 Claims App'x.):

> wherein said needle hub comprises a plurality of flanges extending from its distal portion, said flanges being located a predetermined distance from a wall projecting orthogonally from said needle hub, a space being defined between said flanges and said wall circumferentially about said needle hub, and wherein said collar comprises a plurality of protrusions at the inner wall of its proximal portion, said protrusions being dimensioned to fit to said space when said collar is mated to said needle hub, said collar rotatable about said needle hub after matingly fitted to said space.

Although claim 17 was rejected over Johnson, Crawford, Hudon, and Pressly, the Examiner does not explain how features of that claim, such as the "plurality of flanges" and the "plurality of protrusions," are accounted for in the prior art. Neither is it apparent to where those features are disclosed in the prior art. We note that claims 7 and 26, which are dependent respectively on claims 1 and 20, include features similar to those introduced in claim 17. Claims 7 and 26 are not rejected and were indicated by the Examiner as containing allowable subject matter. (Office Action mailed December 1, 2008, p. 6.)

Smiths Medical challenges the rejection of claim 17 based on its similarity to allowed claims 7 and 26. (App. Br. 21.) In the absence of a response by the Examiner to Appellant's specific challenge, we do not sustain the rejection of claim 17.

Claim 18

Claim 18 is dependent on claim 11. The Examiner rejected claim 18 over Johnson, Crawford, Hudon, Pressly and Landis. Smiths Medical states

that claim 18 includes similar subject matter as claims 8 and 27 and urges that the same argument advanced for claims 8 and 27 is applicable to claim 18.

As discussed above, we rejected Smiths Medical's arguments made in connection with claims 8 and 27. We also reject those arguments as applied to claim 18.

We sustain the rejection of claim 18 over Johnson, Crawford, Hudon, Pressly and Landis.

E. CONCLUSION

1. The Examiner correctly determined that, in connection with a safety needle assembly, Crawford and Hudon together teach a collar that is rotatably mounted directly to a needle hub.

2. The Examiner correctly determined that the prior art teaches first and second engage mechanism formed, respectively as a circumferential rib formed on the inner wall of a collar and a circumferential groove formed on the end of a sheath.

3. The Examiner correctly determined that the prior art discloses a needle hub with an end for connecting to a luer, *i.e.*, a luer end, and a "ring" surrounding the luer end which a user may readily grasp.

4. The Examiner correctly determined that in light of the prior art, it would have been obvious to incorporate a "window" into the surrounding "ring" of a needle hub which allows for viewing of the end of the needle hub.

5. The Examiner correctly determine that the prior art discloses a safety apparatus for a needle assembly including a pair of angled lips where the "respective angles of said lips being varied along the length of said

housing to effect a guide for said needle to smoothly enter into said housing at an angle through said opening."

6. The Examiner did not establish an adequate basis for rejecting claim 17 over the teachings of Johnson, Crawford, Hudon, and Pressly.

F. ORDER

The decision to reject claims 1, 2, 4, 9, 20, 21, 23, and 28 under 35 U.S.C. § 103(a) as unpatentable over Crawford and Hudon is affirmed.

The decision to reject claims 8 and 27 under 35 U.S.C. § 103(a) as unpatentable over Crawford, Hudon, and Landis is affirmed.

The decision to reject claim 10 under 35 U.S.C. § 103(a) as unpatentable over Crawford, Hudon, and Gyure is affirmed.

The decision to reject claims 5 and 24 under 35 U.S.C. § 103(a) as unpatentable over Crawford, Hudon, and Johnson is affirmed.

The decision to reject claims 11, 13-16, and 19 under 35 U.S.C. § 103(a) as unpatentable over Johnson, Crawford, Hudon, and Pressly is affirmed.

The decision to reject claim 17 under 35 U.S.C. § 103(a) as unpatentable over Johnson, Crawford, Hudon, and Pressly is reversed.

The decision to reject claim 18 under 35 U.S.C. § 103(a) as unpatentable over Johnson, Crawford, Hudon, Pressly, and Landis is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART